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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LARRY D. PASKAR

Appeal 2008-004496
Application 09/931,466
Technology Center 3700

Decided: January 29, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 19-22, 24, 26, 28, 29, and 32, directed to a method of using a combination catheter. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

“Selective catheterization of cerebral and visceral branch arteries is often difficult and . . . sometimes requires multiple catheter exchanges for various shaped catheters” (Spec. 1).

The present invention is directed to a method of using “a catheter which can mimic almost any catheter configuration, and can thereafter be reformed in the body to other desired shapes,” particularly “out-of-plane” shapes. The method “obviates the need for multiple catheter exchanges, thereby reducing the time involved in a medical procedure and . . . the possibility of complications” (Spec. 3, 6).

Claims 19, 21, 29, and 32 are representative of the subject matter on appeal:

19. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.

21. The method of using a combination catheter as set forth in claim [19 further including the step of positioning the combination catheter in a desired position, and using the combination catheter in a medical procedure while the distal end of the combination catheter is disposed substantially out of the first plane, and] further including the step of reforming the distal end of the catheter into a substantially different shape.

29. The method of using a combination catheter having a catheter tube and an inner medical element, said combination catheter having a proximal end and a distal end, the method comprising:

disposing a catheter tube in a human body, said catheter tube having a distal end portion fixed in a first curve such that the distal end portion of the catheter tube defines a first plane;

disposing an inner medical element in the catheter tube, said inner medical element having a distal end;

forming the combination catheter into a first shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed substantially out of the first plane;

forming the combination catheter into a second shape, different from the first shape, in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element;

proximally fixing the inner medical element against translation and rotation with respect to the catheter tube while the distal end of the combination catheter is disposed in the second shape.

32. The method as set forth in claim 19 wherein the forming step includes rotating the inner medical element with respect to the catheter tube.

The Examiner relies on the following evidence:

Saice	US 3,970,089	Jul. 20, 1976
Ganz et al.	US 4,430,083	Feb. 7, 1984
Petruzzi	US 4,474,174	Oct. 2, 1984
Patel	US 4,577,621	Mar. 25, 1986
Quinn	US 4,580,573	Apr. 8, 1986
Carpenter	US 4,586,491	May 6, 1986
Ueda	US 4,617,914	Oct. 21, 1986
D'Amelio et al.	US 4,659,195	Apr. 21, 1987
Foerster et al.	US 4,905,667	Mar. 6, 1990
Weldon	US 5,195,990	Mar. 23, 1993

Sylvanowicz	US 5,267,982	Dec. 7, 1993
Voda	US 5,401,258	Mar. 28, 1995
Kiemeneij	US 6,723,083 B2	Apr. 20, 2004

T. TAKAHASHI, ATLAS OF THE HUMAN BODY 66 Harper Collins Publishers, (1994).

In addition, Appellant relies on the following evidence:

Affidavit of Dr. Guiseppe Aliperti, M.D., filed November 4, 2005, under the provisions of 37 C.F.R. § 1.1.32 (hereinafter, “Affidavit”).

The Examiner rejected the claims as follows:

- (A) Claims 22 and 29 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
- (B) Claims 19-22 under 35 U.S.C. § 102(b) as anticipated by Ganz.
- (C) Claims 24, 26, 28, and 32 under 35 U.S.C. § 103(a) as unpatentable over Ganz and Saice.
- (D) Claims 19-22 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sylvanowicz alone or further in view of Voda, Weldon, and Kiemeneij.
- (E) Claims 22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sylvanowicz alone or further in view of Voda, Saice, Quinn, Weldon, Kiemeneij, and Carpenter.
- (F) Claims 19-22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 103(a) as unpatentable over Petruzzi, D’Amelio, Ueda, US Patent class/subclass 600/148, and Takahashi.
- (G) Claims 19-22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 103(a) as unpatentable over D’Amelio, Ueda, US Patent class/subclass 600/148, Forester, and Patel.

(A): WRITTEN DESCRIPTION

Issue

The Examiner rejected claims 22 and 29 as failing to comply with the written description requirement because the claims “have steps that require a time period in which a procedure is performed with two out of plane shapes” but the Examiner “cannot find this sequence of events in the original specification or claims” (Ans. 4).

Appellant contends that the present Specification is the same as the Specification of Patent No. 6,623,449 (the parent of this application), and both Specifications teach that a primary goal of the invention is “the reformation of the catheter from one ‘desired shape’ to another ‘desired shape’” in the body, and the desired shapes can be “out of plane” (App. Br. 53). Appellant contends that “the whole purpose of a ‘desired shape’ in a catheter is to use that ‘desired shape’ in a medical procedure” (*id.*).

The issue raised by this rejection is whether the Examiner has established that the Specification lacks written descriptive support for a method that requires reforming the catheter from one out-of-plane shape to another out-of-plane shape, while the catheter is in the body, and using both shapes in a medical procedure.

Findings of Fact

FF1 According to the Specification as originally filed, one of the objects of the invention is “provision of . . . a catheter which can mimic almost any catheter configuration, and can thereafter be reformed in the body to other desired shapes . . . obviat[ing] the need for multiple catheter exchanges, thereby reducing the time involved in a medical procedure and also reducing the possibility of complications” (Spec. 3).

FF2 The Specification, as originally filed, discloses a combination catheter comprising a controllable sheath and an inner catheter or other medical element with a “complex memory curve” (Spec. 10).

[W]hen the inner catheter or element is fixed at . . . [a] rotational position, such as ninety degrees, with respect to the longitudinal axis of [a] predetermined region of weakness of the sheath . . . [t]he curved nature of the inner surgical element . . . causes the exposed end of the inner surgical element to be disposed substantially out of the plane P containing the predetermined rotational reference position. . . [A] whole family of these “out of plane” curves can be achieved as desired by the user by curving the sheath more or less and exposing more or less of the inner catheter or element.

(Spec. 20.)

Principles of Law

“The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not.”

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003).

“In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue.” *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Rather, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. *See id.*

Analysis

The Examiner acknowledges that the Specification “demonstrates a plurality of shapes that may be formed by manipulating the inner catheter and the outer catheter bodies . . . [and] demonstrate[s] that an out of plane

shape may be made” (Ans. 4), but finds that the claims “go[] beyond the mere forming of shapes and . . . [have] steps that require a time period in which a procedure is performed with two out of plane shapes” (*id.*). The Examiner “does not find this specific sequence of events . . . in the specification” (*id.*).

Appellant contends that “one of the goals of the present invention is to easily and simply reshape a catheter to sequentially catheterize multiple cerebral and visceral branch arteries” (App. Br. 54), without having to change catheters during the procedure.

Appellant’s argument is persuasive. The Specification, as originally filed, clearly conveys the concept of reshaping the catheter into multiple desired shapes, including out-of-plane shapes, while still in the body, in order to avoid multiple catheter exchanges during a procedure (FF1, FF2). This is all that is required to satisfy the written description requirement. The Specification need not provide *in haec verba* support for the claimed subject matter.

Conclusions of Law

The Examiner has not established that the Specification lacks written descriptive support for a method that requires reforming the catheter from one out-of-plane shape to another out-of-plane shape, in the body, and using both shapes in a medical procedure.

We reverse the rejection of claims 22 and 29 as failing to comply with the written description requirement.

(B): ANTICIPATION

Issue

The Examiner rejected claims 19-22 as anticipated by Ganz. The issues raised by this rejection are as follows:

With respect to claims 19 and 20, has Appellant established that the Examiner erred in finding that Ganz describes forming a combination catheter, which has a catheter tube and an inner medical element, into a shape in which the distal end of the combination catheter is disposed substantially out of plane for a period of time sufficient to permit medical use of the inner medical element?

With respect to claims 21 and 22, which depend indirectly from claim 19, has Appellant established that the Examiner erred in finding that Ganz describes reforming the combination catheter from the first shape into a substantially different shape, while still in the body?

Findings of Fact

FF3 The Specification discloses an embodiment of a combination catheter 31 which “includes an enabling sheath 33, and an inner catheter 35 having a distal tip with a complex curve shape” (Spec. 9).

FF4 “[S]heath 33 is formed with a curved distal end” (Spec. 11), and “[i]nner catheter 35 is a complex memory curve catheter which runs in a coaxial manner through enabling sheath 33” (*id.* at 10).

FF5 “Enabling sheath 33 modifies the extreme natural curvature of catheter 35 by acting as a housing that irons out various segments of the curvature when the catheter is retracted back into the sheath” (Spec. 11).

FF6 “[V]arious shapes of the catheter can be selected by advancing or retracting the catheter into the enabling sheath, thereby allowing or

disallowing the natural memory curves to form at various segments” (Spec. 13).

With the complex tip [of inner catheter 35] completely extended beyond the sheath, the most complex tip configuration reforms. By pulling the inner catheter back through the enabling sheath to varying degrees (sheathing and unsheathing the inner catheter tip), various segments of the curve are straightened or “ironed out” - - thereby changing the overall catheter tip configuration and tip orientation. The inner catheter is the active primary component but is a passive passenger with respect to the enabling sheath which acts upon the catheter to modify its shape.

(*Id.* at 10.)

FF7 In addition, as discussed above (*see* FF2), the Specification explains that “rotating the inner surgical element [or catheter] with respect to the sheath results in entire new families of catheter shapes” (Spec. 20).

FF8 Claim 19 is directed to a method of using a combination catheter, where the combination catheter comprises a catheter tube and an inner medical element. The method comprises disposing a catheter tube in a body, where the catheter tube has a distal end portion fixed in a first curve that defines a first plane; disposing an inner medical element in the catheter tube, where the inner medical element has a distal end; and forming the combination catheter into a shape in which the distal end is disposed out of the first plane for a period of time sufficient to permit medical use of the combination catheter.

FF9 Claim 21 depends indirectly from claim 19 and further includes “the step of reforming the distal end of the combination catheter into a substantially different shape.”

FF10 Ganz describes a catheter which can be “advanced directly through . . . [an] angiography catheter into the coronary arterial vasculature” (Ganz, col. 1, ll. 39-40).

FF11 Ganz teaches that:

[A] straight catheter can be utilized to reach a clot in the right coronary artery, whereas passage-seeking bend sections should be used to facilitate insertion of the catheter into the left descending coronary artery . . .

For catheters . . . which have a passage-seeking bend section, it is important that this bend section emerge from the distal opening of the angiography catheter at the correct angular orientation. . . . [O]rientation is automatically provided as the catheter is passed through the angiography catheter by providing the inner catheter with at least one orientation bend section in its distal end portion . . . [which] cooperates with a bend section of the angiography catheter to angularly orient the passage-seeking bend section. The angiography catheter may contain two bend sections, and in this case, the inner catheter can . . . include two corresponding orientation bend sections cooperating with the two bend sections . . . of the angiography catheter. In a preferred configuration, the orientation bend sections of the inner catheter will roughly correspond in configuration and spacing to the bend sections of the angiography catheter so that the orientation bend sections are within the bend sections of the angiography catheter when the passage-seeking bend section is just outside the distal opening of the angiography catheter.

(Ganz, col. 2, l. 55 to. Col. 3, l. 14.)

FF12 “[I]n one preferred construction, the orientation bend sections [of the inner catheter] lie in the same plane, and the passage-seeking bend section lies in a plane transverse to the plane of the orientation bend sections” (Ganz, col. 3, ll. 27-31).

FF13 “The bend sections of the catheters . . . are flexible and resilient” (Ganz, col. 7, ll. 61-62), thus, the bends of the inner catheter will “resiliently seek[] their natural or unstressed condition, and this they are allowed to do when they are within the associated bend sections” of the angiography catheter (*id.* at col. 7, ll. 35-38).

FF14 Thus, advancing the inner catheter through the angiography catheter aligns the orientation bends in the inner catheter with the orientation bends in the angiography catheter to properly angularly orient the passage-seeking bend section of the inner catheter. (Ganz, col. 7, ll. 21-44.)

FF15 The Examiner finds that “[s]uch a process involves the formation of the combination catheter in which the shape of the distal end is disposed substantially out of the first plane” (Ans. 6).

Principles of Law

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

During examination, the PTO must interpret terms in a claim using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Nevertheless, “courts must not ‘import[] limitations from the specification into the claim.’ . . . [I]t is improper to ‘confin[e] the claims to th[e] embodiments’ found in the specification” *In re Trans Texas*

Holdings Corp., 498 F.3d 1290, 1299 (Fed. Cir. 2007) (citations omitted, bracketed text in internal quotes in original).

Analysis

Claims 19 and 20

Appellant contends that:

[Claim 19] requires the step of “disposing an inner medical element in the catheter tube” and the additional step of “forming the combination catheter into a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of at least one of the catheter tube or the inner medical element.” Ganz et al. does not provides [sic] such a feature. In Ganz, the inner catheters are shaped so that the step of disposing the inner catheter in the outer tube forms the desired shapes. There is no separate “forming” step in Ganz.

(App. Br. 19.) Appellant contends that “[e]lement 105 in Ganz is in fact merely a preformed bend in inner catheter 11a” (*id.* at 16), and “the orientation bends 101 and 103 cooperate with the bends in the outer catheter 57a to automatically orient the bend section 105 in the proper direction . . . the inner catheter is not designed to be rotatable, it is designed to emerge at a single, unchanged orientation” (*id.* at 17).

Appellant’s argument is not persuasive as it is premised on an unduly narrow interpretation of what is actually claimed. While the Specification describes an embodiment where new shapes are formed by rotating the inner surgical element within the catheter tube (FF7), claim 19 doesn’t require a forming step that involves rotating the inner medical element. As explained in the Specification, the shape of the distal end of the combination catheter can be formed by simply “advancing or retracting the catheter into the enabling sheath, thereby allowing or disallowing the natural memory curves

[of the inner medical element] to form at various segments” (FF6). We agree with the Examiner that this is precisely what Ganz teaches - that is, Ganz teaches that the flexible, resilient bend sections of the inner catheter seek their respective unstressed shapes as the inner catheter is advanced through, and emerges from, the angiography catheter (FF11-FF14). Therefore, we agree with the Examiner’s finding (FF15) that Ganz discloses the forming step required by claims 19 and 20.

Claims 21 and 22

Claims 21 and 22 depend indirectly from claim 19 and include “the step of reforming the distal end of the combination catheter into a substantially different shape.”

Appellant contends that the claims require “reform[ing] the catheter already in place” (App. Br. 19), but Ganz “requires two separate inner catheters . . . to obtain two different shapes” (*id.*).

Appellant’s argument is persuasive. Ganz doesn’t describe reforming the distal end of the inner catheter from one shape to another. Rather, Ganz uses an inner catheter with a straight distal end to reach the right coronary artery, and replaces it with another inner catheter, with a passage-seeking bend section at the distal end, to reach the left descending coronary artery (FF11).

Conclusions of Law

With respect to claims 19 and 20, Appellant has not established that the Examiner erred in finding that Ganz describes forming a combination catheter into a first shape in which the distal end of the combination catheter is disposed substantially out of plane for a period of time sufficient to permit medical use of the inner medical element.

With respect to claims 21 and 22, Appellant has established that the Examiner erred in finding that Ganz describes reforming the combination catheter from the first shape into a substantially different shape, while still in the body.

The rejection of claims 19-22 as anticipated by Ganz is affirmed with respect to claims 19 and 20, and reversed with respect to claims 21 and 22.

(C): OBVIOUSNESS

Issue

The Examiner rejected claims 24, 26, 28, and 32 as unpatentable over Ganz and Saice. The issues raised by this rejection are as follows:

Has Appellant established that the Examiner erred in concluding that it would have been obvious to proximally fix the distal end of Ganz's inner catheter in an out of plane position relative to Ganz's angiography catheter, given the teachings of Ganz and Saice?

Has Appellant established that the Examiner erred in concluding that it would have been obvious to proximally fix Ganz's inner catheter against translation and rotation relative to Ganz's angiography catheter, given the teachings of Ganz and Saice?

Additional Findings of Fact

FF16 Claim 24 depends from claim 19 and requires "proximally fixing the distal end of the combination catheter substantially out of plane." Claim 26 also depends from claim 19 and requires "proximally fixing the inner medical element against translation and rotation with respect to the catheter tube." Claim 28 is an independent claim that requires "proximally

fixing the inner medical element against translation and rotation with respect to the catheter tube.”

FF17 Saice discloses “a cardiovascular catheter seal device adapted to adjustably seal the extracorporeal or distal end of an emplaced catheter sheath” (Saice, col. 1, ll. 57-60), “so as to prevent passage of blood through the chamber exteriorly of the lumen during catheterization” (*id.* at col. 2, ll. 61-63). Saice explains that:

A catheter [17] may be passed through the device, and into and through a sheath affixed to its proximal end. The device comprises a hollow rigid body defining a chamber which contains an elastomeric member [14] having a lumen through which the catheter is passed. By distending the elastomeric member to constrict the lumen, a seal against egress of blood along the interface between catheter and the innermost surface of the member is effected.

(*Id.* at col. 1, ll. 60-68.)

FF18 Saice designates the extracorporeal end of the catheter sheath assembly as the distal end, while Appellant designates the extracorporeal end as the proximal end (*see* FF17).

FF19 “Once the catheter has been advanced through the seal device-catheter sheath assembly to a desired extent, the elastomer member is fully distended. Thereafter, until member 14 is relaxed, catheter 17 is immovably held by engagement therewith” (Saice, col. 3, ll. 21-25).

FF20 The Examiner finds that “[s]uch immobilization thus includes preventing rotation as well as extension of the inner catheter out of the sheath” (Ans. 7).

Principles of Law

“[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). As long as some suggestion to combine the elements is provided by the prior art as a whole, the law does not require that they be combined for the reason or advantage contemplated by the inventor. *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992); *In re Kronig*, 539 F.2d 1300, 1304 (CCPA 1976).

Analysis

With respect to claims 24, 26, and 28, Appellant contends that Ganz “lacks any proximal fixing feature and does not need such a feature” (App. Br. 30), since Ganz “discloses a system where the inner catheter(s) and the outer tube are formed to have a particular orientation with respect to each other . . . result[ing] in ‘fixing’ at the distal end of the catheter, not at the proximal end” (*id.*).¹

The Examiner acknowledges that Ganz doesn’t disclose a “step in which the inner surgical element is fixed” at the proximal end (Ans. 7). However, the Examiner cites Saice as evidence that “it was known to provide sealing members within cardiac catheterization sheaths for sealing and immobilizing the inner catheter with respect to the outer sheath” to prevent blood loss during catheterization (*id.*), and finds that “[s]uch immobilization thus includes preventing rotation as well as extension of the inner catheter out of the sheath” (*id.*).

¹ Appellant has not addressed claim 32, therefore, it stands or falls with claims 24, 26, and 28 (37 C.F.R. § 41.37(c)(1)(vii) (2006)).

Appellant contends that “Saice adds nothing to Ganz, since there would be no motivation to add such a feature” (App. Br. 30).

Appellant’s argument is not persuasive. The Examiner has identified a reason to modify Ganz by incorporating the extracorporeal (i.e., proximal) sealing arrangement provided by Saice - i.e., to prevent blood loss. Appellant has not explained why it wouldn’t have been obvious for one skilled in the art to seal the interface between Ganz’s inner catheter and angiography catheter to prevent blood loss. The Examiner’s reason for incorporating such a feature does not have to be the same as Appellant’s to establish obviousness. Moreover, Appellant hasn’t established that sealing wouldn’t have fixed the inner catheter against rotation or translation relative to the angiography catheter. As discussed above, Saice teaches that once the sealing mechanism is fully engaged, the inner catheter is immovably held in the catheter sheath (FF20).

Conclusions of Law

Appellant has not established that the Examiner erred in concluding that it would have been obvious to proximally fix Ganz’s inner catheter in an out of plane configuration relative to the angiography catheter, given the teachings of Ganz and Saice,

Nor has Appellant established that the Examiner erred in concluding that it would have been obvious to proximally fix Ganz’s inner catheter against translation and rotation, given the teachings of Ganz and Saice.

The rejection of claims 24, 26, 28, and 32 as unpatentable over Ganz and Saice is affirmed.

(D) and (E): ANTICIPATION/OBVIOUSNESS

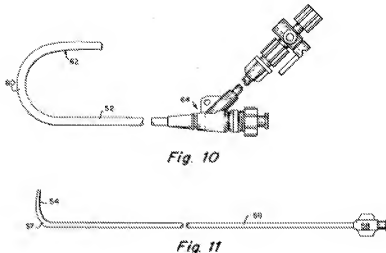
Issue

The Examiner rejected claims 1-22 as anticipated by or, in the alternative, as obvious over Sylvanowicz alone or further in view of Voda, Weldon, and Kiemeneij, and claims 22, 24, 26, 28, 29, and 32 as anticipated by or, in the alternative, as obvious over Sylvanowicz alone or further in view of Voda, Saice, Quinn, Weldon, Kiemeneij, and Carpenter.

The dispositive issue raised by both of these rejections is the same: Has Appellant established that the Examiner erred in concluding that Sylvanowicz describes or suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of the inner medical element?

Findings of Fact

FF21 Figures 10 and 11 of Sylvanowicz show a catheter assembly comprising “an inner catheter 50 and an outer sheath 52” (Sylvanowicz, col. 6, ll. 42-43). Figures 10 and 11 are reproduced immediately below:



Figures 10 and 11 of Sylvanowicz depict the outer sheath 52, and the inner catheter 50, respectively, of a catheter assembly.

FF22 The Examiner finds that the “Judkins type curve (60)” of the “catheter/sheath system” depicted in Figures 10 and 11 of Sylvanowicz “provide[s] a fixed curve in a ‘distal end portion’ of the catheter so as to define a plane” (Ans. 8).

FF23 The Examiner finds that “the inner catheter is taught to be rotated in going from the left coronary artery to the right, [therefore] the distal end of the inner catheter will be formed in an out of the plane configuration with the plane defined by the outer sheath, for a sufficient time to perform medical use of the inner catheter, namely a recatheterization of the coronary arteries by rotation” (*id.* at 9).

FF24 According to Sylvanowicz, “[t]he outer sheath [52] has a relatively large radius curve 60 formed adjacent its distal end and a *straight distal segment 62 extending from the curved portion 60*” (Sylvanowicz, col. 6, ll. 53-56 (emphasis added)), while “[t]he inner catheter 50 is straight except for its distal tip which may be curved at substantially a right angle to define a transversely extending tip segment 54” (*id.* at col. 6, ll. 46-48).

FF25 “The relatively sharp radius bend 57 in the [inner] catheter will define the secondary curve of the catheter assembly and the larger radius curve in the sheath cooperates with the catheter 50 to define the primary bend 60” (Sylvanowicz, col. 6, ll. 56-60).

FF26 Figures 12-14 of Sylvanowicz, which depict the catheter assembly of Figures 10 and 11 in use, are reproduced immediately below:

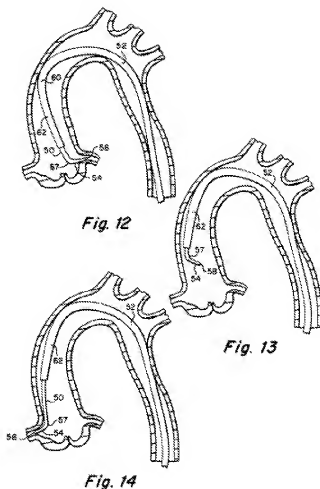


Figure 12 “shows the catheter assembly placed in the patient’s aorta with the tip segment 58 of the inner catheter 50 intubated in the left coronary ostium” (Sylvanowicz, col. 7, ll. 32-34).

After the angiographic study of the left coronary artery has been completed, the right coronary artery may be studied by manipulating the catheter assembly to intubate the distal end 58 of the inner catheter 50 in the right coronary artery ostium as shown in FIG. 14. . . . [T]hat is achieved simply and quickly as illustrated in FIGS. 13 and 14 by combined withdrawal of the sheath 52 and rotation of the inner catheter 50. . . . By withdrawing the sheath proximally to reposition the primary curve, the [straight] distal segment 62 is reoriented and points toward the right coronary ostium. Thus, when extended, the position of the protruding distal portion of the inner catheter

shifts from the position as shown in FIG. 12 toward a position toward the right coronary ostium. The inner catheter 50 may be rotated about its longitudinal axis approximately 180° to direct the distal tip 58 toward the right coronary ostium so that as the distal portion of the catheter 50 continues to shift it will bring the tip 58 into the right coronary ostium.

(*Id.* at col. 7, ll. 35-57.)

Analysis

Appellant contends that the distal end portion 62 of Sylvanowicz's outer sheath 52 is straight (App. Br. 21), and the outer sheath 52 and inner catheter 50 are co-linear at the point where the inner catheter exits the outer sheath (*id.* at 23). Since "the distal portion of the inner catheter points toward the right coronary ostium . . . [when] the straight distal segment 62 [of the outer sheath] points toward the right[] coronary ostium," Appellant contends that "those two elements must be in the same plane" (*id.* at 23).

Appellant's argument is persuasive. Sylvanowicz explicitly states that "[t]he outer sheath [52] has . . . a straight distal segment 62 extending from the curved portion 60" (FF24), and the distal ends of both the outer sheath and the inner catheter point into the right (or left) ostium in use (FF26). We agree with Appellant that the straight distal segment 62 of the sheath and the distal portion of the inner catheter 50, including the tip 54, are in the same plane, and Sylvanowicz's device "is incapable of providing the . . . interaction of two curved distal end portions which result[s] in the inner element being thrown out of plane with respect to the outer catheter tube" (App. Br. 22), a feature which is required by all the rejected claims. The additional references cited by the Examiner fail to remedy this deficiency;

therefore, we agree with Appellant that Sylvanowicz doesn't suggest the required feature, even in combination with the additional references cited.

Conclusions of Law

Appellant has established that the Examiner erred in concluding that Sylvanowicz describes or suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of the inner medical element.

The rejection of claims 1-22 as anticipated by or, in the alternative, as obvious over Sylvanowicz alone or further in view of Voda, Weldon, and Kiemeneij is reversed.

The rejection of claims 22, 24, 26, 28, 29, and 32 as anticipated by or, in the alternative, as obvious over Sylvanowicz alone or further in view of Voda, Saice, Quinn, Weldon, Kiemeneij, and Carpenter is also reversed.

(F): OBVIOUSNESS

Issue

The Examiner rejected claims 19-22, 24, 26, 28, 29, and 32 as obvious over Petruzzi, D'Amelio, Ueda, US Patent class/subclass 600/148, and Takahashi.

The dispositive issue raised by this rejection is: Has Appellant established that the Examiner erred in concluding that the cited evidence suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out

of the first plane for a period of time sufficient to permit medical use of the inner medical element?

Findings of Fact

FF27 The Examiner finds that Petruzzi discloses a “method in which an outer catheter, in the form of endoscope 40, [is] positioned in a manner such that it . . . form[s] an out of plane configuration” with “an inner surgical element tube 56 or element 58” (Ans. 15).

FF28 Flexible shaft 40, catheter 56 and working end 58 are shown in Petruzzi's Figure 3, an enlarged partial sectional view of the distal tip of a flexible endoscope, reproduced immediately below:

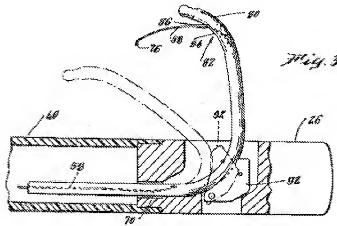


Figure 3 of Petrucci shows the relative positions of elements 40, 56, and 58 in Petrucci's device (Petrucci, col. 3, ll. 46-47; col. 4, l. 1. 19, 64, 67).

FF28 Affiant Dr. Guiseppe Aliperti states that he is “familiar with and use[s] endoscopic instruments of the type disclosed in the Petruzzi patent” (Affidavit, 1st page), and that “the catheter is advanced out of the endoscope in the same direction the camera of the endoscope is facing” (*id.*, 2nd page), i.e., “[t]he camera and the catheter both point perpendicularly from the side of the endoscope and are in the same plane” (*id.*).

Analysis

Appellant contends that “Petruzzi has a straight distal portion of the outer tube whose longitudinal axis is in the same plane as the distal portion of a curved inner element” (App. Br. 31). As explained in the Affidavit of Dr. Giuseppe Aliperti, “[d]irect visualization of the ampulla of Vater requires that the endoscope camera be pointing at the ampulla, in the same direction the catheter subsequently extends. The camera and the catheter both point perpendicularly from the side of the endoscope and are in the same plane” (Affidavit, 2nd page).

Therefore, Appellant contends, Petruzzi doesn’t “allow[] the formation of various out-of-plane shapes in the body . . . and then the use of the formed shape in the medical procedure” as required by the rejected claims (App. Br. 36).

We agree with Appellant that the Examiner has not shown that Petruzzi suggests this requirement of all the rejected claims. The additional evidence cited by the Examiner does not remedy this deficiency, therefore, we agree with Appellant that Petruzzi doesn’t suggest the required feature, even in combination with the additional references cited. Moreover, the Examiner has not acknowledged or addressed Dr. Aliperti’s Affidavit.

Conclusions of Law

Appellant has established that the Examiner erred in concluding that Petruzzi, with or without the additionally cited evidence, suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for

a period of time sufficient to permit medical use of the inner medical element.

The rejection of claims 19-22, 24, 26, 28, 29, and 32 as obvious over Petruzzi, D'Amelio, Ueda, US Patent class/subclass 600/148, and Takahashi is reversed.

(G): OBVIOUSNESS

Issue

The Examiner rejected claims 19-22, 24, 26, 28, 29, and 32 as obvious over D'Amelio, Ueda, US Patent class/subclass 600/148, Forester, and Patel.

Again, the dispositive issue raised by this rejection is: Has Appellant established that the Examiner erred in concluding that the cited evidence suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of the inner medical element?

Findings of Fact

FF29 D'Amelio discloses an inspection device comprising "a flexible outer sleeve or tubular guide member which is readily articulated in four directions . . . [and] includes an optical system for the transmission of illuminating light and the viewing of reflected light" (D'Amelio, col. 3, ll. 23-27).

Analysis

Appellant contends that "[t]he entire purpose of D'Amelio et al. is to point an optical inspection apparatus toward the area of interest" (App. Br.

50), and the reference doesn't disclose or suggest "shaping and forming as required by the claims" (*id.* at 38).

We agree with Appellant that the Examiner has not shown that D'Amelio suggests that "out-of-plane [shapes] as defined in the claims . . . [would be] desirable or even possible" with the disclosed device for the reasons articulated on pages 38-52 of Appellant's Brief. The additional evidence cited by the Examiner does not remedy this deficiency, therefore, we agree with Appellant that D'Amelio doesn't suggest the required out-of-plane feature, even in combination with the additional references cited.

Conclusions of Law

Appellant has established that the Examiner erred in concluding that D'Amelio, with or without the additionally cited evidence, suggests using a combination catheter - with a catheter tube with a curved distal end in a first plane and an inner medical element - to form a shape in which the distal end of the combination catheter is disposed substantially out of the first plane for a period of time sufficient to permit medical use of the inner medical element.

The rejection of the claims as obvious over D'Amelio, Ueda, US Patent class/subclass 600/148, Forester, and Patel is reversed.

SUMMARY

- (A) The rejection of claims 22 and 29 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is reversed.
- (B) The rejection of claims 19-22 under 35 U.S.C. § 102(b) as anticipated by Ganz is affirmed with respect to claims 19 and 20, and reversed with respect to claims 21 and 22.

- (C) The rejection of claims 24, 26, 28, and 32 under 35 U.S.C. § 103(a) as unpatentable over Ganz and Saice is affirmed.
- (D) The rejection of claims 19-22 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sylvanowicz alone or further in view of Voda, Weldon, and Kiemeneij is reversed.
- (E) The rejection of claims 22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sylvanowicz alone or further in view of Voda, Saice, Quinn, Weldon, Kiemeneij, and Carpenter is reversed.
- (F) The rejection of claims 19-22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 103(a) as unpatentable over Petruzzi, D'Amelio, Ueda, US Patent class/subclass 600/148, and Takahashi is reversed.
- (G) The rejection of claims 19-22, 24, 26, 28, 29, and 32 under 35 U.S.C. § 103(a) as unpatentable over D'Amelio, Ueda, US Patent class/subclass 600/148, Forester, and Patel is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

dm

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